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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/559,984 04/26/00 HUBBELL

J 50166/002001

HM12/1009

EXAMINER

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DI NOLA BARON, L

ART UNIT	PAPER NUMBER
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1615

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DATE MAILED:

10/09/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/559,984	HUBBELL ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Liliana Di Nola-Baron	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on \_\_\_\_\_.  
 2a) This action is **FINAL**.                  2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-18 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_ is/are allowed.  
 6) Claim(s) 1-18 is/are rejected.  
 7) Claim(s) \_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 11) The proposed drawing correction filed on \_\_\_\_ is: a) approved b) disapproved by the Examiner.  
     If approved, corrected drawings are required in reply to this Office action.  
 12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
 \* See the attached detailed Office action for a list of the certified copies not received.  
 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
 a) The translation of the foreign language provisional application has been received.  
 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

The examiner acknowledges receipt of Applicant's amendment, filed on August 23, 2001.

### ***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1, 5 and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Amiel et al.

The claimed invention refers to a hydrogel precursor comprising a polymer and a protecting group.

Amiel et al. discloses hydrophobically end-capped polyethylene oxide and water-soluble  $\beta$ -cyclodextrin polymers (See e.g., Abstract and Introduction). Said polymers meet the limitations of claims 1, 5 and 9 of the instant application, as they contemplate a hydrogel precursor comprising a polymer and a protecting group, specifically cyclodextrin. Thus, Amiel et al. anticipates the claimed invention.

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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4. Claims 1-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Amiel et al. as applied to claims 1, 5 and 9 above, and further in view of Hedstrand et al., Rhee et al. and Jodal et al.

The claimed invention refers to a hydrogel precursor comprising a polymer and a protecting group. Additionally, the claimed invention refers to a hydrogel precursor comprising a polymer and a protecting group and a molecule that disrupt the interaction between the polymer and the protecting group, and methods for forming a hydrogel or incorporating a biological material into a hydrogel.

The teachings of Amiel et al. have been summarized above. Amiel et al. does not include hydrocarbon groups among the hydrophobic interacting groups of the polymer and does not disclose methods of incorporating drugs into the hydrogel.

Rhee et al. discloses biocompatible compositions, formed by covalently binding natural inert polymers to synthetic hydrophilic polymers, such as polyethylene glycol (See e.g., col. 2, lines 1-8). Rhee et al. includes dextrans, such as cyclodextrin, among the natural polymers used in the invention and teaches that the compositions may include active proteins, such as cytokines (See e.g., col. 2, lines 9-27). Rhee et al. teaches that the compositions are formulated in a flowable form and injected into the patient, and after injection, the carrier is removed (See e.g., col. 2, lines 48-59). Rhee et al. teaches that in order to form the conjugates of the invention, the hydrophilic polymer, specifically PEG, is functionalized by various methods, including addition of chloride (See e.g., col. 10, lines 3-38).

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Hedstrand et al. provides structured copolymers and discloses their use as gels (See e.g., col. 1, lines 33-34). Hedstrand et al. teaches that the modified dendrimers of the invention are prepared by capping the dense star polymers with a hydrophobic tail (See e.g., col. 4, lines 59-67).

Hedstrand et al. explains that the amine- or hydroxy-terminated dendrimers are reacted with a hydrocarbon chloride or bromide (See e.g., col. 5, lines 1-6). Hedstrand et al. teaches that the selection of the hydrophobic groups is within the capability of one skilled in the art (See e.g., col. 5, lines 46-51).

Jodal et al. discloses enzymatic degradation of cyclodextrin with  $\alpha$ -amylase (See e.g., Introduction and Discussion).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the hydrogel precursors disclosed by Amiel et al. or Rhee et al., by including a molecule, such as an  $\alpha$ -amylase, to disrupt the interaction between the polymer and cyclodextrin. Because of the teachings of Hedstrand et al., that selection of the hydrophobic groups is within the capability of one skilled in the art, one of ordinary skill in the art would have a reasonable expectation that hydrogel precursors, in which the polymer has fluoride functional groups, would be successfully formed and able to incorporate biological material. Therefore the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

***Response to Arguments***

5. Applicant's arguments filed on August 23, 2001 have been fully considered but they are not persuasive.

6. In response to Applicant's argument, that the prior art (Amiel et al.) uses cyclodextrins in a very different way from the use in the instant application, it is noted that claim 1 reads on a composition and a feature intended use has no patentable weight in a composition claim.

7. In response to Applicant's argument, that the hydrophobically end-capped PEO chains disclosed by the prior art (Amiel et al.) are not capable of assembling into a gel until the cyclodextrins are added, it is noted that Amiel et al. teaches that hydrophobically modified polymers exhibit unusual aqueous solution behavior, with the appearance of thickening properties above certain polymer concentration (see e.g., Introduction). Thus, the polymers of the prior art are capable of assembling into a gel without the addition of cyclodextrin.

***Conclusion***

Applicant's amendment has overcome the objections to claims 3, 4 and 11-13 of the previous Office action.

Claims 1-18 stand rejected.

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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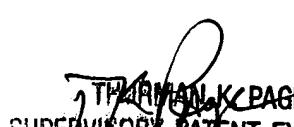
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Liliana Di Nola-Baron whose telephone number is 703-308-8318. The examiner can normally be reached on Monday through Thursday, 5:30AM-4:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3592 for regular communications and 703-305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 308-1234/ 1235.

October 1, 2001

  
THURMAN K. PAGE  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600